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Draft regulations for field trials of genetically modified crops.

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N/A

Report Highlights: The Ministry of Agriculture and Rural Development (MARD) recently notified these draft regulations to the WTO under SPS number 08-0186, with a final date for comments of March 7, 2008. This English version was provided by MARD and was only minimally edited by Post. These regulations are expected to be approved by mid 2008 and to take effect by the end of 2008.

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MINISTRY OF AGRICULTURE &
RURAL DEVELOPMENT

SOCIALIST REPUBLIC OF VIET NAM
Independence – Liberty – Happiness

REGULATIONS ON BIOSAFETY MANAGEMENT OF GENETICALLY MODIFIED CROPS

CHAPTER I GENERAL REGULATIONS

Article 1. Scope

This regulation defines the governmental management on field trials for risk assessment activities and issue of biosafety certification for genetically modified crops (GMCs) purposed as plant variety and the biosafety management in production, trade, import and export of GM plant variety in Viet Nam.

Article 2. Objectives

This Regulation is applied to domestic and foreign organizations, individuals applying for the biosafety certification of GMC (herein referred to as “applicants”). Domestic field trial conductor (herein referred to as “Trial conductor”), organizations, individuals related to risk assessment activities and issue of safety certification for genetically modified crops (GMCs) purposed as plant variety and organizations, individuals, who do the production, trade, import and export of GM plant variety in the territory of Viet Nam.

Article 3. Definitions

For the purpose of this regulation:

1. *Genetically modified crops* (abbreviated as “GMCs”) are those partially or fully plants that contain genetic information which can breed or materials for breeding new crops whose genetic materials are modified by gene-transferring technology for usage purpose as plant varieties.
2. *GM plant variety* are Genetically modified crops recognized as plant varieties having permission for production and trade in Vietnam by MARD, including seeds, tubers, fruits, rootstalks, branches, seedling leaves, shoots, flowers, tissue, cell, spore.
3. *Gene flow* is the transfer of gene(s) from GMCs to other plant relatives even to other plant non-relatives.
4. *Release of GMCs* is deliberate release of GMCs into environment.

5. *Risks* are the influence of undesired factors which harmfully affect human health, biodiversity and environment and which are directly and/or indirectly caused by GMCs-related activities.

6. *Risk assessment* is the activity to define the latent risk and damage level which has previously occurred, and/or currently occurs or may occur in the future in GMCs-related activities over human health.

7. *Risk management* is the activity to conduct safety methods to prevent, handle and repair risks in GMCs-related activities which may affect human health, environment and biodiversity.

8. *Trial for Risk assessment* (abbreviated as “trials”) is the activity to evaluate the biosafety level of GMCs on the environment and biodiversity in concrete conditions of Viet Nam in order to issue the biosafety certification before bringing them into production and trade.

9. *Transformation event* is the activity to insert one target gene into a fixed position on the chromosome in order to create GMCs lines.

10. *Advisory Council of GMCs Biosafety Management (ACGBM)* established by MARD includes scientists, and management officers having experience and working in fields related directly to biosafety. Department include at least 9 members in charge of evaluating the registration documents, field trial documents and consulting to Minister of MARD about biosafety of GMCs.

11. *Risk supervision organization* (abbreviated as “Supervision organization”) is a group of scientists and management officers, who have experience and working in fields related directly to biosafety, are given the assignment to evaluate the risk assessment field trials for GMCs in order to find out and solve on time the unsafe cases may occur during the trial process.

12. *Biosafety certification of GMCs* is MARD’s documents recognizing that GMCs were assessed and guaranteed the safety for environment and biodiversity and had the approval for trials.

CHAPTER II

FIELD TRIALS RISK ASSESSMENT OF GMCs

Article 4. General regulations for trials

1. All GMCs must be passed field trials risk assessment before cultivation.
2. MARD will issue the trial certification for only GMCs basing on the conclusion of Advisory Council of GMC Biosafety Management (ACGBM).
3. MARD recognize organizations and individuals having enough condition for trials and assess only the trial result of the conductor recognized.

Article 5. Registration for risk assessment trials

1. Condition for registration for trials
 - a. Domestic products

Domestic GMCs is the result of the science research process checked and taken over by authorized Government office.

b. Imported products:

- Having the permit for usage as seeds of the original country
- Being risk assessed in the specific condition of the original country
- Being established the effective safety management by the original country

2. Registration documents

a. Registration form (conformed to Appendix 1)

b. Certificates of products and/or recognition of research results:

- For overseas products: Patents documents demonstrating ownership at the place of origin.
- For domestic products; Approval certificate of Ministry's Committee for Science and Technology required

c. Document of technique explanation and the risk assessment of the Applicants (conformed to Appendix 2, 3)

d. Biosafety certificate or the equivalent documents at the place of origin.

3. Documents submission:

Applicants should submit all documents (listed in Item 2, Article 5) to the Department of Science & Technology, MARD (DST-MARD).

Within 5 days of receipt of application documents, DST-MARD shall send to applicants the letter to confirm the receiving documents.

In case of incomplete documents, DST-MARD shall require the applicants to supplement them. Time needed for supplementing additional information is not included in appraisal period of application document.

Article 6. Documents appraisal and issuing the permit for trials

1. DST-MARD shall base on the documents of the applicants, and submit to the Minister of MARD and make a decision to establish the Advisory Council of GMC Biosafety Management (ACGBM) to assess the registration documents for trials.

2. DST-MARD shall conduct appraisal of valid application documents and bring out the conclusion about the biosafety of GMCs basing on the documents provided.

3. DST-MARD shall summarize conclusions of ACGBM and the other assessment conclusions and propose to Minister of MARD for issuing GMC field trial approval, in which the volume of GMCs having the approval to import (for imported products) or having the permit for usage (for domestic products) with the trial purpose. In case approval is not issued, DST-MARD shall have to notify the applicant with detailed reasons in written document.

5. Period of appraisal and issuing the trial certification is 60 days. The trial registration applicant shall assume responsibility for supplying additional information as required by

appraiser authorities. Time needed for supplementing additional information is not included in appraisal period of application document.

6. MARD shall notify about the issuing the trial certification of GMCs to Ministry of Natural Resources and Environment (MONRE).

Article 7. Trial conductors

1. Conditions for trial conductor

- a) Acquiring sufficient facilities and constructions, equipments, technical procedures and man power appropriate for risk assessment trial of specific GMC
- b) Ready to apply methods for risk supervision and management during trial period;
- c) Having the Field for trial, ensure safely for public, environment and production areas followed regulations of MARD.

2. Steps of approval of trial conductor

- a) Documents submission: Applicants should submit following documents to the Department of Science & Technology, MARD (DST-MARD), include:
 - Registration form;
 - Report on man power, constructions and technical facilities of the applicants;
 - Copies of decisions of functions and tasks of the applicants
- b) DST-MARD shall examine all documents and facilities of the applicants followed regulations of MARD and propose Minister of MARD to issue the certification of Trial conductor.

Article 8. Trials for risk assessment

1. Principle of trials for risk assessment

- a. Risk assessment trials of GMCs shall be conducted gradually. Small scale trials will be conducted first and then large scale trials, that depends specifically on the crops and criteria
- b. If there are any uncontrollable risk detected at any step of risk assessment process, trials shall have to be cancelled immediately
- c. Type, time and scale of trials shall be detail regulated in “Technical guideline for risk assessment on environment and biodiversity” for each kind of GMCs.

2. Content of trials for risk assessment

- a. Gene flow
- b. Stability and expression of gene inserted;
- c. Effects on environment and biodiversity
 - Target organisms;
 - Non-target organisms;

3. Steps of trials

- a. After receiving permit for trials, applicants should contact the trial conductor that has assigned in the trial permission to make the contract of GMC trials;
- b. Trial conductor shall define the area of field trial conduction;
- c. After getting official letter of agreement for field trial conduction of Provincial People's Committee where the trials will be conducted. Trial conductors shall conduct the trials according to the "Technical guideline for risk assessment on environment and biodiversity" conforming to the specific GMCs.
- d. Trial conductor shall have to submit reports of GMC trials for risk assessment to DST-MARD within 30days after trials have finished.

Article 9. Risk supervision

1. Before conducting trial for risk assessment, the trial conductor shall inform to the DST-MARD the plan of whole trials and risk management
2. Based on GMC applied for trials, the trial location and risk management plan, DST-MARD propose to MARD to nominate the trial supervisor.
3. The responsibilities of the Supervision organization
 - a. Building up the supervisory plans and organizing regular and irregular inspection to detect and settle the risk that may occur during the trials period.
 - b. Having the right to stop the trials and inform to MARD about the solutions if any violations of regulation or uncontrolled risk detected
 - c. Within 15days after the process of supervision finished, Supervision organization has to report to MARD by the written documents. These reports are important documents for appraising the result of trials.

Article 10. Information management of field trials for risk assessment of GMCs

1. Besides the registration documents at Item 2, Article 5, Paragraph a, Item 2, Article 7, Applicants, Trial conductors and Supervision organization shall assume responsibility for providing all documents and related information to DST-MARD during trial conduction period. It includes:
 - a. New information related to GMCs applied for trials from Applicants;
 - b. Periodical and final reports on the trial results from Trial conductors;
 - c. Reports on the regular and irregular inspections; reports on the solutions for the risk occurred during the trials, and the final reports on the trial supervision provided by Supervision organization;
 - d. Other related information about GMCs applied for trials which are collected and revised by Trial conductors and Supervision organization.
2. Applicants, Trial conductors, Supervision organization, and DST-MARD are responsible of security of all information above and published only when getting MARD's approval. Applicant shall determine obviously confidential information to all related organizations in order to ensure the legalization of provided information.

Article 11. Responsibility of Applicants and related organizations, divisions

1. Applicant shall assume responsibility for providing sufficient information of GMC to DST-MARD
2. Applicant shall have responsibility for paying for registration fees, and other charges related to trials according to the current regulations
3. Trial conductor, Supervision organization and other organizations, individuals related to trial process have to strictly comply with this Regulation and assume their own responsibilities for results.

CHAPTER III

APPRAISAL OF TRIAL RESULTS AND ISSUING BIOSAFETY CERTIFICATION FOR GMCs

Article 12. Appraisal trial results

1. DST-MARD is responsible of assessment for the registration documents and evaluate the trial result.
2. Steps of appraisal trial result
 - a. Applicant, trial conductor, Supervision organization organizations shall submit the reports and related information conformed to Item 1, Article 10 to DST- MARD.
 - b. DST-MARD shall examine all documents and to submit to 2 professional organizations or 2 independent experts for critical review.
 - c. After getting the ideas of 2 professional organizations or 2 experts, DST-MARD and other related units shall complete the documents (conformed to Appendix 4) and organize the conference for Advisory Council of GMCs Biosafety Management (ACGBM). ACGBM shall conduct to examine the trial result and give the conclusion about the safety of GMCs to effect to environment and biodiversity.
3. Time needed for appraisal is 30 days since the date of receipt of completed application documents. During the period assessment, if DST-MARD requires the related units to provide complete information or assess the reality on the location, time needed for supplementing additional information is not included in appraisal period of application document.

Article 13. Issuing the biosafety certification of GMCs

1. DST-MARD collect all ACGBM's conclusions, propose to Minister of MARD to issue the "Biosafety Certification" of GMCs with the usage purpose as seeds.
2. In case of GMCs can be used as foods, materials for food and medicine processing, MARD shall issue the biosafety certification, when the Ministry of Health assessed the risk of this product and recognized its safety to human health in written documents.
3. "Biosafety Certification" shall be issued to only GMCs having transformation event conducted in a field trial. This certification is valid within 5 years. After 5 years, the applicants need to re-register. MARD shall regain "Biosafety Certification" in case of

GMCs used for the wrong purpose as regulations (even legal proceedings has not yet been solved) or recognition any possibly arisen risks of GMCs harmfully affecting human health, and environment and biodiversity.

4. MARD shall appraise and issue “Biosafety Certification” of other GMCs having the same transformation event after getting the result of the trials in large scales by the same trial conductor; or GMCs are the result of the project checked and taken over by the same level as ministries and recognized by Council and Ministry of Project Management .

5. In case the “Biosafety Certification” of GMCs is not issued, MARD shall send to applicants the letter with detailed reasons.

6. MARD shall notify about the issuing the “Biosafety Certification” of GMCs to Ministry of Natural Resources and Environment.

CHAPTER IV

PRODUCTION, TRADE, IMPORT, EXPORT AND RISK MANAGEMENT OF GENETICALLY MODIFIED PLANT VARIETIES

Article 14. Production, trade and import of GMCs varieties

Organizations, individuals who produce, trade, export, import GMCs varieties have responsibilities as follow:

1. Complying with all current regulations of plant varieties management and biosafety regulation on the GMO import, export and trading issued by Ministry of Trade and Industry.
2. Regularly monitoring, supervising the safety level on human health, environment, and biodiversity
3. Handling risk, compensate for all damages and paying for all charges of repairing risk consequence when uncontrolled risk happened.
4. Producing, trading, and importing varieties that included in the list of plant varieties approved to use in Vietnam promulgated by MARD.

Article 15. Export of GMCs varieties

GMCs that exported to overseas have to comply with all legal export regulations of Vietnam, and the importing country and international conventions that Social Republic of Vietnam has signed or joined.

Article 16. Risk management

1. All trials, production and trade, export and import activities of GMCs have to strictly comply with risk preventive, handling and repairing methods if risk occurred.
2. Trial conductors and organizations, individuals who produce, trade, import and export GMCs shall assume responsibility for applying appropriate methods of risk management for timely preventing, detecting risk(s) in order to handle and repair risk consequence. Incase of detecting risk(s) during implementation process, applicants have to report to MARD, Ministry of National Recourses and Environment (MNRE) for cooperated handling.

3. In case of risk of the GMC that applied for trial is detected in other countries, applicants assume responsibility for notifying Trial conductors and Trial supervisors. Organizations, individuals and related units have to implement immediately the risk controlling methods and report to MARD and MNRE for management.

CHAPTER V IMPLEMENTATION ORGANIZATION

Article 17. Responsibilities of MARD's authorized organizations

MARD shall unite governmental management of GMCs biosafety nationwide and make concrete assignments for authorized organizations as follow:

1. Department of Science and Technology (DST-MARD)

DST-MARD is a key governmental organization, shall assume responsibility for assisting Minister of MARD in uniting management organization and carrying out duties related to trials for risk assessment and issue of "Biosafety Certification" of GMCs. In addition, DST-MARD has the duties as follow:

a. Setting up and proposing Minister of MARD for promulgating the "Operation status of the Advisory Council of GMCs Biosafety Management (ACGBM)"

b. Organizing appraisal and proposing Minister of MARD for issuing the permit for importing GMC materials or GMC seeds for research and trials purpose.

c. Building up and proposing Minister of MARD to promulgating the "List of GMCs approved for trial for plant varieties usage purpose in Vietnam"

2. Department of Cultivation and Department of Forestry

a. Building up and proposing Minister of MARD to promulgating the "List of GMCs approved for production and trade purpose in Vietnam"

b. Organizing the governmental management of GMCs biosafety within the assigned sphere of control.

Article 18. Responsibilities of Centrally-led municipal/Provincial People's Committees

Centrally-led municipal and provincial People's Committees that shall direct relevant Departments of Agriculture and Rural Development assume their responsibilities for:

1. Implementing the activities of governmental management on GMCs biosafety at local region.

2. Organizing propaganda, education to improve community awareness of GMCs

3. Planning sites for GMCs trials and production at local region.

4. Organizing inspection activities and handling violations within their own jurisdiction to the activities related to GMCs at local region.

Article 19. Violations Handling

1. Organizations, individuals violate the regulations on biosafety management on GMCs will be applied the disciplinary measures depending on the violation level such as

administrative punishment, damage compensation, consequence repair, or criminal responsibility according to the law.

2. Strictly forbidding organizations, individuals who have behavior of usage and release GMCs without the MARD's approval. Organizations, individuals violate the regulations, will be applied the disciplinary measures depending on the violation level.

CHAPTER VI EXECUTION PROVISION

Article 20. Implementation organization

1. DST – MARD shall co-ordinate with related organizations to instruct, organize, and verifying the implementation of this regulation.

2. DST-MARD shall assume responsibility for reporting to Minister of MARD if there are any difficulties occurring during implementing process to have timely consideration and modification.

PP. MINISTER OF AGRICULT. & RURAL DEV.
DEPUTY MINISTER

Appendix 1

SOCIALIST REPUBLIC OF VIET NAM
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**APPLICATION FOR TRIALS REGISTRATION
 OF GENETICALLY MODIFIED CROPS**

1. Genetically modified crops (GMC) name:
2. GMC scientific name:.....
3. Transferred gene:.....
4. GMC commercial name:.....
5. Property of transferred gene:.....
6. Purposes of registration:.....
7. Anticipation of using form, scale and site after registration:.....

8. Name of organization producing GMC:.....
9. Name, address of registering organizations:.....

10. Address in Viet Nam:.....

11. Registering form:

- Initial First registration <input type="checkbox"/>	- Additional registration <input type="checkbox"/>
- Re-registration <input type="checkbox"/>	
12. Enclosed documents and specimens:
 1.
 2.
 3.
 4.
 5.

In.....[locality].....,[date].....
 Signature and seal

Full name:.....
 Position:.....

Appendix 2**REQUIRED INFORMATION FOR TRIALS FOR RISK ASSESSMENT AND ISSUE
BIOSAFETY CERTIFICATE FOR GENETICALLY MODIFIED CROPS****I. General information**

1. Name, address of the organization/individual applying for registration
2. Name, address of the representative of the organization/individual applying for registration
3. Name, address of the organization/individual breeding genetically modified crops

II. Information related to the transformed-gene donor/recipient plant

4. Sufficient name of the GMC used in trials
 - Common name:
 - Family:
 - Genus:
 - Species:
 - Subspecies:
 - Variety/breed:
5. Information of reproduction
 - Properties of GMC's reproduction,
 - Reproduction model,
 - Special factors affecting the reproduction,
 - Duration of a generation.
 - Crossing compatibility between cultivated and wild varieties.
6. Information of survival possibility of GMC
 - Ability of survival or dominant forms.
 - Special factors affecting the survival possibility.
7. Information of dispersion possibility of GMC
 - Forms and abilities (scale) of dispersion
 - Special factors affecting the dispersion possibility
8. Geographical distribution of the GMCs; the sites applying the GMCs which are not cultivated in Viet Nam; botanical characteristics of the crops.
9. Interaction possibility between GMCs with other crops in the same ecological system, including information related to the toxins affecting human, other animals and organisms.

III. Information related to the genetic transformation

10. Description of genetic transformation methodology.
11. Natural properties and the used vectors.
12. Size and functions of the gene, the organisms donating the whole gene and/or each component of the genetic complexes.

IV. Information related to the GMC

13. Description of traits and/or characteristics of GMCs, including intended positive traits.
14. The following information of inserted and/or deleted genes:

- Size and structure of the inserted gene, activation methods of the gene, including the information related to any component of the vector introduced to the GMC or any exogenous DNA-carrying material remaining in the GMC.

- Size and structure of the deleted gene.

- Site of the gene inserted into GMC (in incorporation in chromosome, chloroplast, and mitochondrion or in free forms) and identification methods.

- Number of copies of the inserted gene.

15. Information of trait expression of the gene inserted into the GMCs.

- Information related to the expression of the inserted gene and activation methods.

- The GMC's organs (tissues in roots, stem, seeds or pollens) in which the gene expression is obtained

16. Information of differences of GMCs from the parent plants or recipient plants:

- Reproduction methodologies and rate.

- Dispersion ability.

- Survival ability.

17. Sustainability of the inserted gene.

18. Possibility of transferring the genetic material from GMC to other organisms.

19. Information of toxins and harmful effects on human health and environment generated from the genetic modification.

20. Interaction mechanism between GMCs with the target organisms.

21. Interaction possibility between GMCs and unintended organisms.

22. Description of detection and recognition technology for GMCs.

23. Pre-release information of GMCs.

V. Information related to release sites *(in case of field trial release)*

24. Release scale and sites.

25. Ecological features of the release sites, including climate, floristic and faunal compositions.

26. Reproductive compatibility of GMCs with other non-GMCs in the same family, and wild plant species at the release sites.

27. Adjacent areas of the release sites which can be affected with protection areas and the buffer zone.

VI. Information related to release

28. Aims of release.

29. Planned point of time and release time.

30. Methods used for release of GMC.

31. Methods used for controlling and managing the release sites before, during and after the release, including cultivation, harvest, transport, storage and safe hygiene.

32. Planned scale (area), number of individuals or weight of GMC to be released.

VII. Plans of management, supervision after release, and waste treatment

33. Description of warning plans

- For maintaining the GMC apart from reproductively-compatible species (minimizing the preventing the spread of seeds and pollens).

34. Description of methods used for treatment of the sites after releasing.

- 35. Description of methods used for treatment of materials from GMC after release, including waste treatment.
- 36. Description of plans and methods of management.
- 37. Description of plan of action in case of emergency.

VIII. Information of possible effects of GMC release on environment

- 38. Possibility of higher tolerance in GMCs than that of non-GMCs of same species, of parent plants in same cultivation conditions or dominance over other species in the same natural ecological system.
- 39. Advantages/disadvantages related to compatible species which can lead to gene flow from GMCs into other organisms.
- 40. Possible effects on environment due to interaction between GMCs and target and non-target organisms.

IX. Data and results of previous releases of GMCs (if any)

- 41. Data and results of previous releases of GMCs which organizations/individuals are submitting for registration, particularly the field trials' results, risk management effectiveness.

X. Data of previous applications for release (if any)

- 42. Detailed data of previous applications for release of GMCs in Viet Nam. The provided data should include number of applications, approved documents and other related documents.

XI. Risk assessment and risk assessment announcement

- 43. Announcement of evaluation of effects and risks on human health and environment caused by release of GMCs which the organizations/individuals are submitting for field trials of registration.

XII. Legal status of confidential information

- 44. Evident identification of related information which should be kept commercially confidential for legal guarantee of provided information.

Appendix 3**REPORTING OF RISK ASSESSMENT****I. General information**

1. Name, address of Applicant
2. Name, address of the Representative of Applicant
3. Name, address of organization/individual breeding the GMCs
4. Sufficient name of GMCs
 - Common name:
 - Family:
 - Genus:
 - Species:
 - Subspecies:
 - Variety/breed:

II. Content of report

1. Defines characteristic(s) of the GMC that may cause bad effect on human health, environment and biodiversity
2. Defines risks that have which has previously occurred or may occur in the future, level of effect on the receiving environment of GMCs
3. Evaluation of consequence and level of damage of each kind of risk
4. Defines the risk(s) that can be accepted or managed and concrete conditions, methods of management
- 5.

III. Applicant's commitment

... *Date.... Month.... Year*

Applicant or the Representative of Applicant

(Sign, full name and stamp)

Appendix 4**APPRAISAL DOCUMENT OF EVALUATION
FOR TRIALS RISK ASSESSMENT OF GMC**

1. Application for checking and taking over the **results of trial for risk assessment**
2. Summarized Report of the results of GMC trial for risk assessment.
3. Total report of the results of GMC trial for risk assessment.
4. Report of the results of periodical and unscheduled supervisions.
5. Report of the results of total supervision of field trial process.
6. Opponent remarks of 2 professional organizations.
7. Record book of field trial for risk assessment.
8. Record book of experimental raw data.
9. Specimen of GMC or its derived product.
10. Confirmation of provincial authority where the trial conducted.